IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

AZURITY PHARMACEUTICALS, INC., Plaintiff, v. BIONPHARMA INC., Defendant.	C.A. No. 3:21-cv-12870-MAS-DEA [redacted] *Document Filed Electronically*

REPLY BRIEF IN SUPPORT OF PLAINTIFF AZURITY PHARMACEUTICALS, INC.'S ORDER TO SHOW CAUSE FOR TEMPORARY RESTRAINING ORDER, PRELIMINARY INJUNCTION, AND OTHER EMERGENT RELIEF

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CASES

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’023 Patent	U.S. Patent No. 11,040,023 (D.I. 1-1)
’008 Patent	U.S. Patent No. 9,669,008
’442 Patent	U.S. Patent No. 9,808,442
’987 Patent	U.S. Patent No. 10,154,987
’745 Patent	U.S. Patent No. 10,039,745
’868 Patent	U.S. Patent No. 10,772,868
’482 Patent	U.S. Patent No. 10,786,482
’621 Patent	U.S. Patent No. 10,918,621
ACE	Angiotensin converting enzyme
ANDA	Abbreviated New Drug Application
Azurity	Plaintiff Azurity Pharmaceuticals, Inc.
Bionpharma	Defendant Bionpharma Inc.
Bionpharma’s ANDA	ANDA No. 212408
Bionpharma’s ANDA Product	Product that is the subject of Bionpharma’s ANDA No. 212408
B. Dec.	Declaration of Graham Buckton, Ph.D.
B.R.	Reply Declaration of Graham Buckton, Ph.D. (filed herewith)
D.I. 38	Bionpharma’s Opposition to Azurity’s Motion to Show Cause
D.I. 39	Declaration of Robert McSorley in Support of Bionpharma’s Opposition to Azurity’s Motion to Show Cause
D.I. 42	Declaration of Christian Moreton, Ph.D. in Support of Bionpharma’s Opposition to Azurity’s Motion to Show Cause
Epaned®	EPANED® (enalapril maleate) Oral Solution, 1 mg/mL
Ex.	Exhibits attached to the Declaration of Wendy L. Devine, filed with the original Motion for an Order to Show Cause For Temporary Restraining Order, Preliminary Injunction, and Other Emergent Relief, or Exhibits attached to the Supplemental Declaration of Wendy L. Devine (filed herewith)

FDA	U.S. Food & Drug Administration
Patel Decl.	Declaration of Amit Patel
Patel Supp.	Supplemental Declaration of Amit Patel (filed herewith)
POSA	Person of ordinary skill in the art
RTU	Ready-to-Use
Stec Decl.	Declaration of Jeffery A. Stec, Ph.D.
S.R.	Reply Declaration of Jeffery A. Stec, Ph.D. (filed herewith)

** Unless otherwise noted, all emphasis is added, all internal quotations and citations are omitted, and all "D.I." citations are to the docket in C.A. No. 21-12870 (D.N.J.).

I. INTRODUCTION

Bionpharma does not deny that its ANDA Product infringes the '023 Patent. Instead, Bionpharma contends that the '023 patent (which is presumed valid) is invalid on the basis of misstated legal standards and faulty analysis. For example, Bionpharma contends that the patent must contain working examples of every claimed formulation (something the law does not require). Bionpharma also largely ignores the extensive disclosures of the specification apart from the working examples. These legally unsupported arguments do not raise a substantial question regarding validity. Likewise, Bionpharma's claim preclusion argument is entirely based on an incorrect interpretation of the legal standard that, if applied, renders absurd results, and is insufficient to avoid an injunction.

Azurity is suffering irreparable harm each day Bionpharma's infringement is permitted to continue. Monetary damages cannot adequately compensate Azurity for the irreversible damage to its business. The balance of the harms weighs toward Azurity given that Bionpharma orchestrated this situation by flagrantly disregarding this Court's rules requiring that it provide Azurity with its request to FDA for final approval (which was required to be produced on July 14). Had Bionpharma complied with the rules, Azurity could have sought an injunction prior to any launch of the infringing product. The real-world status quo—not the pretextual one that Bionpharma contrived—is obtained by enjoining Bionpharma. Finally,

Bionpharma's claim that the public good favors no injunction is meritless—willful infringement can never be in the public interest.

II. AZURITY IS LIKELY TO SUCCEED ON THE MERITS

Bionpharma does not dispute that its ANDA Product meets every limitation of claims 1-6, 10, 12-16, and 19 of the '023 Patent. D.I. 38. To avoid liability for that infringement, Bionpharma offers only invalidity and claim preclusion arguments that do not survive scrutiny.

A. THERE IS ADEQUATE WRITTEN DESCRIPTION

1. Bionpharma ignores the perspective of a POSA

Bionpharma's written description arguments fail because it fails to apply the perspective of a POSA. The issue to be addressed is not whether the patent provides description sufficiently identifying the invention such that a POSA "would understand the inventors to have possessed the invention at the time of filing." *Alcon Research Ltd. v. Barr Labs.,* Inc., 745 F.3d 1180, 1190-91 (Fed. Cir. 2014). When assessed from that perspective, there is clear written description for the claims.

Bionpharma's emphasis on statements regarding the instability of enalapril alone in water misses the point. Those statements represent the problem solved by the claimed formulation and are irrelevant to whether the claims are adequately supported. B.R., ¶24. A POSA would understand the '023 Patent's inventors solved this problem with their inventive formulation and in their patent taught the appropriate ingredients for the claimed formulation along with parameters to

promote stability, specifically pH and temperature. B.R., ¶17.

Bionpharma's contention that the '023 Patent contains no description of stable enalapril liquids without a buffer is also wrong. D.I. 38 at 17. The '023 Patent describes liquid enalapril formulations without a buffer. D.I. 1-1, 13:58-59; B.R., ¶ 38. Furthermore, a POSA would understand—from common knowledge and the specification that the stable liquid enalapril formulations of the claims do not require a buffer. B.R., ¶34. For example, a POSA would understand (1) a solution at a pH will stay at that pH absent the introduction of an acid or a base, regardless of the presence of a buffer, and (2) only acids or bases resulting from the degradation of formulation components could change the pH of a formulation during storage. *Id.*, ¶¶35-36. From the specification, a POSA would understand the only degradant of enalapril affecting pH would be enalaprilat, as it alone has ionizable hydrogens (carboxyl groups). D.I. 1-1, 14:27-40; B.R., ¶36. A POSA would also recognize from the '023 Patent that the degradation of enalapril produces nominal amounts of enalaprilat, and thus the pH would not change dramatically during storage regardless of the presence of a buffer. *Id.*, ¶¶37-39.[1] *Id.*

Bionpharma's contention that a number of aspects of the claims are not described is also wrong. D.I. 38 at 18-20. Contrary to Bionpharma's arguments,

[1] Indeed, the specification shows that the claimed formulation is insensitive to the amount of buffer present. B.R., ¶38.

working examples are not a requirement for written description. *Alcon*, 745 F.3d at 1190-91. Bionpharma's arguments also fail for at least the following reasons:

Paraben Preservative Formulations: The patent teaches that pH is a key parameter for stability. Examples C4 and C5 have pH values of 4.4 and 4.6, respectively. D.I. 1-1, Example C; B.R., ¶¶34-39. The specification teaches that stable liquid enalapril formulations should have a pH of less than about 4. B.R., ¶28.

No pH Restriction: The patent teaches a POSA a pH range of below about 4 for stable liquid enalapril formulations. *Id.*, ¶¶26-27.

Buffers Beyond Citric Acid/Sodium Citrate and Concentrations Beyond 5-20 mM: A POSA would understand buffers to be unnecessary in light of the intrinsic properties of the formulation that keep the formulation stable once set at the proper pH and temperature. *Id.*, ¶¶34-39.

Sugars/Sugar Alcohols: The specification teaches the POSA about potential challenges related to certain excipients. *Id.*, ¶21. The specification also teaches how formulations at the same pH and the same storage temperature have similar stabilities regardless of their ingredients. *Id.*, ¶¶30-33.

Sodium Benzoate Concentrations Beyond "about 1 mg/ml": The specification teaches stable liquid enalapril formulations with sodium benzoate concentrations ranging from 0.2 to 1.2 mg/ml that are stable for at least 12 months. D.I. 1-1, 11:4-40, 19:12-13; B.R., ¶17.

Stability Longer Than 12 Months: The specification discloses liquid enalapril formulations with stabilities beyond 12 months, namely at least 18 months and at least 24 months. *Id.*, ¶17.

2. Bionpharma misrepresents the case law

Bionpharma incorrectly argues Azurity is legally precluded from supporting written description with a POSA's knowledge at the time of the invention because of Azurity's prior unexpected results arguments. D.I. 38 at 12. The cases cited by Bionpharma contain no such holding because there is no such rule. A patent "need not include information that is already known and available to the experienced

public." *Zoltek Corp. v. United States*, 815 F.3d 1302, 1308 (Fed. Cir. 2016); *see also Visual Memory LLC v. NVIDIA Corp.*, 867 F.3d 1253, 1261 (Fed. Cir. 2017). Bionpharma citations to *Idenix*, *Nuvo*, and *Pernix* do not show otherwise.[2]

B. THE CLAIMS ARE ENABLED

Bionpharma's enablement arguments mirror its flawed written description arguments. It incorrectly asserts that the claims cover "tens . . . of thousands" of potential formulations by taking the claims out of the context of the specification, then erroneously concluding that it would require undue experimentation to practice the claims. D.I. 38 at 22-24. Bionpharma is wrong.

Bionpharma's argument that the asserted claims are not enabled because of the "sheer breadth of the claims" (*id.* at 24), is wrong. *E.g.*, *Invitrogen Corp. v. Clontech Labs., Inc.*, 429 F.3d 1052, 1071 (Fed. Cir. 2005) (enablement "does not require the inventor to foresee every means of implementing an invention at pains of losing his patent franchise"); *Monsanto Co. v. Scruggs*, 459 F.3d 1328, 1338 (Fed.

[2] In *Idenix*, a specific nucleoside structure was claimed but not disclosed. *Idenix Pharm. LLC v. Gilead Scis. Inc.*, 941 F.3d 1149, 1162-63 (Fed. Cir. 2019). In *Nuvo*, the inventor possessed no more "than a mere wish or hope" that the claimed embodiment was effective and was unable to point to any particular piece of the specification to support that understanding belief. *Nuvo Pharm. (Ir.) Designated Activity Co. v. Dr. Reddy's Labs. Inc.*, 923 F.3d 1368, 1381 (Fed. Cir. 2019). *Pernix* involved a patent that only contained one working example. *Pernix Ir. Pain DAC v. Alvogen Malta Operations, Ltd.*, 323 F. Supp. 3d 566, 628 (D. Del. 2018). In contrast, the '023 Patent claims liquid enalapril formulations with specified ingredients and properties disclosed in the specification, and several working examples. *Supra*, § A(1)(a).

Cir. 2006) (claims to genus enabled where the specification provided multiple examples of species within that genus).[3] Bionpharma ignores guidance from the '023 Patent identifying formulations that would satisfy the claims. B.R., ¶48. A POSA, after reviewing the specification, would see certain ingredients could be combined but would be limited by the specific parameters of the formulation disclosed in the claims, such as the pH. *Id.*, ¶41. It would therefore be routine for a POSA to create the claimed formulation using the knowledge gained from the specification combined with a POSA's general knowledge regarding the use of certain pharmaceutical excipients. *Id.*, ¶¶46, 49-51.

None of Bionpharma's contentions regarding supposed inoperable embodiments are legally valid or factually correct. D.I. 38 at 22. As an initial matter, enablement does not require all embodiments to be operative. *Warner Lambert Co. v. Teva Pharm. USA, Inc.*, No. 99-922(DRD), 2007 WL 4233015, at *12 (D.N.J. Nov. 29, 2007); *see also Atlas Powder Co. v. E.L. du Pont De Nemours & Co.,* 750 F.2d 1569, 1576 (Fed. Cir. 1984). Moreover, Bionpharma's arguments fail to read the claims in light of the specification. Indeed, the specification of the '023 Patent instructs a POSA how avoid issues related to inoperable embodiments. B.R. ¶¶21,

[3] Bionpharma's cited case law—*Idenix*, 941 F. 3d 1149 and *Wyeth & Cordis Corp. v. Abbott Laboratories.*, 720 F.3d 1380 (Fed. Cir. 2013)—are inapposite as each involved patent specifications that gave little to no guidance regarding how to practice the full scope of the claims. That is not the case here. B.R., ¶¶47, 49, 53.

30-33; *Warner*, 2007 WL 4233015 at *11 (patent can be enabled even with 40% of embodiments being inoperable as long as a POSA could select ingredients to create the proper formulation).

First, Bionpharma's arguments that a POSA would understand two Example C liquids, C4 and C5, are inoperable because both lack sufficient stability and that embodiments with a pH beyond 3-3.5 are not enabled are wrong, as they ignore the teaching of the specification. D.I. 38 at 22. A POSA would understand from the specification that the pH of the claimed formulation should be less than about 4 to ensure sufficient stability. B.R., ¶¶26, 28-29. The pH of examples C4 and C5 are 4.4 and 4.6, respectively. Thus, these are not inoperable embodiments, but rather define the scope of the invention by providing experimental validation for the specification's instruction that formulations should have a pH of less than about 4. B.R., ¶44.

Second, Bionpharma's argument that embodiments with parabens and sugars are inoperable is likewise incorrect. D.I. 38 at 22. A POSA would understand from their own knowledge and the specification that there is potential for interactions between certain excipients. B.R., ¶21. Using this understanding, a POSA would know how to create operable formulations within the scope of the claims.

The specification's extensive disclosures inform a POSA how to create the genus of stable, liquid formulations of enalapril claimed in the '023 Patent. *Id.*, ¶¶43,

47. The notion that a POSA would require years' worth of stability testing on any of these formulations, let alone "tens . . . of thousands" of them is unfathomable. Rather, it would be a simple and routine matter for a POSA to practice the full scope of the claims. *Id.*, ¶¶46, 49-51.

C. THE CLAIMS WOULD NOT HAVE BEEN OBVIOUS

Bionpharma's obviousness contention is based entirely on the erroneous assertion that the claimed formulations are "essentially" variants of Epaned® Kit resulting from alleged "routine optimization," including the removal of several excipients. D.I. 38 at 3, 10, 24-26. Neither Epaned® Kit, nor any of Bionpharma's other prior art references, disclose liquid enalapril formulations with the claimed stability.[4] D.I. 25 at 14; B.R., ¶¶5-7. Bionpharma fails to present persuasive evidence of (1) a motivation to modify the Epaned® Kit to achieve the claimed invention, and (2) any evidence that a POSA would have expected success in doing so. B.R., ¶ 7. Despite asserting obviousness, Dr. Moreton readily admits that a

[4] Bionpharma's assertion that the '747 Patent discusses liquid formulations that are stable for up to 36 months (D.I. 38 at 25) is wrong. The '747 Patent only discusses stability for 36 **weeks** (not 36 months). D.I. 43-9, 13:29-33; *cf.* D.I. 42-3, ¶ 201 (recognizing the same). Also, the '747 Patent defines "stability" for oral liquid solutions as 90% enalapril remaining as opposed to the 95% required by the asserted claims. D.I. 43-9, 13:4-10. Finally, the '747 Patent contains no data that would indicate to a POSA that the powder for solution formulations described therein would be stable (with 95% enalapril and 5% or less degradants) as required by the asserted claims. In particular, the data in Example 2 of the '747 Patent do not provide a reasonable expectation of achieving an enalapril solution that is stable for a year or more. B.R., ¶8; *see also* D.I. 42-12 at 858:18-859:10.

POSA would not have expected liquid formulations of enalapril to have the claimed long-term stability and that stability of such formulations is generally unpredictable. *Id.*, ¶10. These admissions cannot be reconciled with Dr. Moreton's conclusory statements of motivation and expected success.

Further, Bionpharma does not address the decades-long gap between allegedly key prior art (IP & Brenner, published 1987) and the claimed invention (2016 priority date), which itself is strong evidence of nonobviousness. *Leo Pharm. Prods., Ltd. v. Rea*, 726 F.3d 1346, 1359 (Fed. Cir. 2013). As explained by Dr. Buckton, there is no motivation to combine or reasonable expectation of success to "reformulate" the Epaned® Kit into the stable (with an increased level and length of stability), liquid formulation recited in the asserted claims.[5] B.R., ¶7.

Finally, Bionpharma's contention regarding a lack of unexpected results is not credible. D.I. 38 at 26. It is undisputed that a POSA would not have expected liquid formulations of enalapril to have the claimed long-term stability. Accordingly, the demonstration of long-term stability of liquid formulations of enalapril in the '023 patent is compelling evidence of unexpected results.[6] In addition, Bionpharma's

[5] Bionpharma suggests that Azurity has argued that the asserted claims are inherently stable. D.I. 38 at 25. Azurity has not, and thus Bionpharma's corresponding arguments are inapposite.

[6] Unexpected results need only be "commensurate in scope" with the claims; absolute identity of scope is not required. *Genetics Inst., LLC v. Novartis Vaccines & Diagnostics, Inc.*, 655 F.3d 1291, 1308 (Fed. Cir. 2011). Bionpharma asserts the claims of the '023 Patent are "commensurate in scope with the claims of the Second

ANDA Product is an undisputed embodiment of the asserted claims, and remains stable for at least 24 months, which is further evidence of the unexpected stability of the claimed invention. B.R., ¶11; *id.*, ¶10 (noting Dr. Moreton's admission that prior to the invention of the asserted claims, liquid formulations of enalapril had expected stability on the order of weeks to a few months). In short, there is no substantial question that any of asserted claims are obvious.[7]

D. CLAIM PRECLUSION DOES NOT APPLY

Bionpharma's contention that a claim preclusion analysis requires an anticipation/obviousness analysis to determine the identicality of claim scope is fundamentally wrong. "The decision in *SimpleAir* . . . did not create a new standard requiring a showing of anticipation or obviousness to satisfy claim preclusion. The decision expressly stated that 'the scope of the asserted patent claims in the two suits' must be 'essentially the same.'" *Google LLC v. SimpleAir, Inc.*, No. 16-cv-03758, 2020 U.S. Dist. LEXIS 172293, at *15 (C.D. Cal. Aug. 20, 2020) (quoting *SimpleAir, Inc. v. Google LLC*, 884 F.3d 1160, 1167 (Fed. Cir. 2018)); *see also XY, LLC v. Trans Ova Genetics, LLC*, 968 F.3d 1323, 1333 (Fed. Cir. 2020) (holding the

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Wave Patents." D.I. 38 at 15 n.5. Accepting that assertion, stability data presented during prosecution of those patents—reflecting stability after 52 weeks—further evidence unexpected results. Ex. 10, Table 2; Ex. 11, Tables 2, 5.

[7] Other objective indicia support non-obviousness of the asserted claims. Epaned® (an embodiment of the asserted claims) is a commercial success (D.I. 42-12 at 1010:12-1016:19), met a long-felt need (*id.* at 940:7-967:25), and received industry praise (*id.* at 968:1-971:1; D.I. 25-2, Ex. 3 at 105:8-110:14).

district court erred by not comparing the scope of the patent claims).

If the scope of the claims of the '023 Patent was "essentially the same" as those of the previously asserted patents, Bionpharma could simply assert the same non-infringement argument it used previously. Yet, Bionpharma does not assert ***any*** non-infringement argument regarding the claims asserted here. This alone demonstrates that ***the scope of the claims is not essentially the same***. For this reason, and for those explained in detail in Azurity's Opposition to the Motion to Dismiss (D.I. 48), claim preclusion does not apply.

III. AZURITY WILL SUFFER IRREPARABLE HARM

After being on the market a mere three weeks, Bionpharma has sold [redacted] units of its generic enalapril oral solution while earning [redacted] in net sales. S.R., ¶¶6-7. Each day that Bionpharma's ANDA Product is on the market, Azurity stands to lose market share, revenue, goodwill, and business opportunities—precisely the sort of evidence that courts routinely find warrant a preliminary injunction.[8] Rather than address the substance of Azurity's evidence of irreparable harm, Bionpharma proffers only meritless arguments. D.I. 38 at 26-29.

Bionpharma's contention that Azurity delayed in seeking emergency relief is

[8] *E.g.*, *Abbot Labs v. Sandoz, Inc.*, 544 F.3d 1341, 1355 (Fed. Cir. 2008) (market share loss and revenue loss); *Aria Diagnostics, Inc. v. Sequenom, Inc.*, 726 F.3d 1296, 1304 (Fed. Cir. 2013) (loss of market share); *Celsis In Vitro, Inc. v. CellzDirect, Inc.*, 664 F.3d 922, 930 (Fed. Cir. 2012) (loss of goodwill, damage to reputation, and loss of business opportunities).

untrue.[9] Azurity filed this action the day the '023 Patent issued. D.I. 1 and 1-1. At that time, Bionpharma had not yet received final FDA approval, nor would it receive final approval until nearly two months later.[10] Bionpharma failed to produce FDA communications as expressly mandated under L. Pat. R. 3.6(j). Bionpharma's excuse for not doing so was that "it was never under any obligation to produce." D.I. 34 at 3 n.5. Precedent in this District holds otherwise.[11] Had Bionpharma complied with the Local Patent Rules, Azurity would have received Bionpharma's request to FDA for final approval on July 14, 2021 and would have immediately sought an injunction. Instead, Azurity was forced to bring the present emergency motion with insufficient time to prevent Bionpharma's launch. Thus, any fault for the timing of Azurity's request lies entirely with Bionpharma.

Moreover, Bionpharma's assertion that Azurity failed to show irreparable harm to itself is unfounded. D.I. 38 at 27; D.I. 39, ¶¶16-17. Azurity—not Silvergate—owns the '023 Patent at issue, owns the Epaned® NDA, and promotes and sells Epaned®. Patel Decl., ¶1, Patel Supp., ¶¶6-10. Thus, any harm resulting

[9] *High Tech Medical Instrumentation, Inc. v. New Image Industries*, is clearly distinguishable. 49 F.3d 1551 (Fed. Cir. 1995). There, the plaintiff delayed bringing its action for ***17 months*** after issuance of the reexamination certificate. *Id*. at 1554.

[10] Contrary to Bionpharma's assertion, there is no evidence that FDA's final approval notification to Bionpharma became public as of August 10, 2021.

[11] As this District recently explained, "[w]hile those communications do not appear to be directly relevant to the question of infringement or validity, they certainly pertain to and concern the central issue in these cases: Defendants' ANDAs." *Jazz Pharm., Inc. v. Amneal Pharm., LLC, et al.*, No. 2:13-cv-00391, D.I. 187 at 5.

from Bionpharma's launch of its product would solely be directed to Azurity. [12]

Bionpharma's suggestion that the importance of Epaned® to Azurity will decline due to Azurity's acquisition of Arbor Pharmaceuticals (D.I. 38 at 29; D.I. 39, ¶47) has no factual basis. S.R., ¶¶26-29. Neither Bionpharma nor its expert offer any support for this assertion, nor can they as it is simply not true. [redacted]. Patel Decl., ¶8; Patel Supp., ¶¶17-20. [13] Until Bionpharma's infringing launch, Azurity [redacted]. Patel Supp., ¶¶16-20. In fact, Azurity [redacted]. *Id*., ¶¶18-19.

Bionpharma erroneously argues that because its expert can allegedly "quantify" lost profits and market share, they cannot constitute irreparable harm. D.I. 38 at 27; D.I. 39, ¶¶20-31. Cases have long recognized that lost profits and market share, when irreversible, may constitute irreparable harm, and may lead to other damages not compensatory with money damages. *E.g., Hoffman-La Roche*

[12] The facts of *Poly-America, L.P. v. GSE Lining Technology, Inc.*, are inapplicable. 383 F.3d 1303, 1311 (Fed. Cir. 2004). *Poly-America* concerned two entities under the control of one parent; one was the patent holder and the other sold the product at issue. *Id*. Here, Azurity owns the patent and markets/sells Epaned®. Patel Supp. ¶7.

[13] Mr. Patel's supplemental declaration is made on the basis of his "understanding from counsel" because, while Mr. McSorley comments on Mr. Patel's opening declaration, Bionpharma refused to provide a copy of Mr. McSorely's declaration that could be shared with Mr. Patel prior to the filing of this brief.

Inc. v. Cobalt Pharm., Inc., No. 07-4539, 2010 WL 4687839, at *12 (D.N.J. Nov. 10, 2010).[14] Lost Epaned® revenue stemming from Bionpharma's at-risk launch would precipitate a cascade of other events—[redacted]—that would make any harm irreparable. Patel Decl., ¶¶21-36; Stec Decl., ¶¶71-74; S.R., ¶14; Patel Supp., ¶20. Taking lost profits in isolation misses the point. *Trebro Mfg., Inc. v. Firefly Equip., LLC*, 748 F.3d 1159, 1170 (Fed. Cir. 2014).

Dr. Stec gave detailed opinions explaining why such harm is not speculative, and indeed, the evidence produced by Bionpharma subsequent to Azurity's original motion supports Dr. Stec's conclusions. S.R., ¶¶6-7, 15. As to Bionpharma's claim that [redacted] are not irreparable, cases holding otherwise are abundant. *E.g.*, *Albany Molecular Research, Inc. v. Dr. Reddy's Labs., Ltd.*, No. 09-4638, 2010 WL 2516465, at *10-11 (D.N.J. June 14, 2010).

IV. BALANCE OF HARDGSHIPS AND PUBLIC INTEREST

Bionpharma's assertion that the balance of hardships favors Bionpharma—after it launched at-risk to a patent it admits that it literally infringes—rings hollow. D.I. 38 at 29. Courts routinely decide that an infringer that acts with knowledge of a patent takes a calculated risk and therefore cannot complain the balance of hardships tips against it.[15] Moreover, Bionpharma's assertion that it will suffer harm

[14] Plavix® is inapplicable. Stec Decl., ¶¶91-104; S.R., ¶¶20-23.
[15] *E.g.*, *Sanofi-Synthelabo, Inc. v. Apotex, Inc.*, 470 F.3d 1368, 1383 (Fed. Cir. 2006)

because it waited for the 30-month stay to end is also without merit. D.I. 38 at 29. A stay mandated by statute is not a hardship, nor is Bionpharma's inability to enter a market with a product that literally infringes Azurity's '023 Patent. Bionpharma's assertion that the public interest weighs in favor of early access to its generic product has also been repeatedly rejected. *E.g.*, *Sanofi-Synthelabo*, 470 F.3d at 1383-84.[16]

V. BIONPHARMA FAILS TO SUPPORT ITS BOND REQUEST

Any bond should only cover Bionpharma's losses while the injunction is in place. *Par Pharm., Inc. v. TWI Pharm., Inc.*, No. 11-2466, 2014 WL 3956024, at *6 (D. Md. Aug. 12, 2014). Bionpharma's bond request is unsupported by evidence and based only on speculation that overestimates its own profits. S.R., ¶¶52-67. Bionpharma bears the burden of establishing an appropriate bond amount and has utterly failed to do so. *LEGO A/S v. ZURU Inc.*, 799 F. App'x 823, 837 (Fed. Cir. 2020) (courts have discretion to "dispense with the bond requirement" where there has been no proof of harm to those enjoined). As explained by Dr. Stec, a more appropriate bond amount ranges between [redacted]. S.R. ¶¶52-67.

VI. CONCLUSION

Azurity respectfully requests that this Court grant this motion.

(harms were the result of "own decision to engage in an at-risk launch"); *Windsurfing Int'l, Inc. v. AMF, Inc.*, 782 F.2d 995, 1003 n.12 (Fed. Cir. 1986).

[16] Bionpharma's cited article is misleading and incomplete. Patel Supp. ¶¶26-30.

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Respectfully submitted,

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